

DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date	10-7-98
Publication Date	10-8
Certifier	<i>[Signature]</i>

21 CFR Part 814

[Docket No. 98N-0168]

Medical Devices; 30-Day Notices and 135-Day PMA Supplement Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing the submission and review of premarket approval (PMA) supplements to provide for the submission of a 30-day notice for modifications to manufacturing procedures or methods of manufacture. Amendments are being made to implement revisions to the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: *(Insert date 30 days after date of publication in the Federal Register.)*

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, the President signed FDAMA (Pub. L. 105-115) into law. As one of its provisions, FDAMA added section 515(d)(6) to the act (21 U.S.C. 360e(d)(6)). This new

section provides that PMA supplements are required for any change to a device that affect safety and effectiveness unless such change involves modifications to manufacturing procedures or method of manufacture. Such changes to manufacturing procedures or method of manufacture will require a 30-day notice or, where FDA finds such notice inadequate, a 135-day PMA supplement.

The agency has developed guidance on this issue entitled “CDRH Guidance for 30–Day notices and 135–Day PMA Supplements for Manufacturing Method or Process Changes for Use by OC, ODE, and Industry,” and has announced the availability of the guidance in the **Federal Register** of February 26, 1998 (63 FR 9570).

On April 27, 1998, FDA published a proposed rule (63 FR 20558) and a direct final rule (63 FR 20530) to implement the amendments to the PMA provisions. FDA received a single comment, which the agency deemed to be significant. Accordingly, consistent with FDA’s procedures on direct final rulemaking, FDA is withdrawing the direct final rule and is addressing the comment in this final rule based upon the April 27, 1998, proposed rule previously referenced. This rule incorporates the provisions for a 30-day notice and 135-day PMA supplements into FDA’s regulations at § 814.39 (21 CFR 814.39).

II. Summary of Comments

The agency received one comment, which stated that the list of examples of changes affecting the safety or effectiveness of a device which would require the submission of a PMA supplement, provided in § 814.39(a), should not include the language in proposed § 814.39(a)(4) which states: “Changes in manufacturing facilities, methods, or quality control procedures that do not meet the requirements for a submission under paragraphs (e) or (f) of this section.” The comment states that no submissions are required for changes that do not affect safety or effectiveness and, under FDAMA, changes in manufacturing facilities, methods, or quality control procedures which DO affect the safety or effectiveness of the device may be filed with a 30-day notice. Therefore, proposed § 814.39(a)(4) does not apply to any submissions, and should be removed.

The agency agrees and is removing proposed § 814.39(a)(4) from the list of changes which require the submission of a PMA supplement. The agency stresses, however, that the 30-day notice procedure is restricted to changes only in manufacturing procedures and methods of manufacture. A PMA supplement would be required if multiple changes are made to a device, even if such changes include changes in manufacturing procedures or methods of manufacture along with other changes which would otherwise require a PMA supplement.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The rule merely codifies applicable statutory requirements imposed by FDAMA. The agency certifies that this final will not have a significant economic impact on a substantial number of small entities. This final rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates

Reform Act because it does not impose a mandate that results in an expenditure of \$100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any 1 year.

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown as follows along with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Supplements to Premarket Approval Applications for Medical Devices

Description: FDAMA added section 515(d)(6) to the act, modifying FDA's statutory authority regarding PMA of medical devices. This new section provides for an alternate form of notice to the agency for certain types of changes to a device for which the manufacturer has an approved PMA. Under this section, PMA supplements are required for all changes that affect safety and effectiveness unless such changes involve modifications to manufacturing procedures or the method of manufacture. For those types of manufacturing changes, the manufacturer may submit to the agency an alternate form of notice in the form of a 30-day notice or, where FDA finds such notice inadequate, a 135-day PMA supplement. The 30-day notice must describe the change the manufacturer intends to make, summarize the data or information supporting the change, and state that the change has been made in accordance with the requirements of part 820 (21 CFR part 820).

The manufacturer may distribute the device 30 days after FDA receives the notice, unless FDA notifies the applicant, within that 30-day period, that the notice is inadequate. If the notice is not adequate, FDA will inform the manufacturer that a 135-day supplement is required and will describe what additional information or action is necessary for FDA to approve the change.

This rule incorporates the provisions for a 30-day notice and 135-day supplements into FDA's regulations at § 814.39 to reflect the changes made by FDAMA.

Description of Respondents: Businesses or other for profit organizations.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.39	493	1	493	66.15	32,612

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA believes that the amendments to § 814.39 permitting the submission of 30-day notices in lieu of PMA supplements will result in approximately a 10 percent reduction in the total number of hours needed to comply as compared to § 814.39. As a result, FDA estimates that the new total number of hours needed to comply with information collection requirements in § 814.39 is 32,612, for a reduction of 3,451 hours.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a document in the **Federal Register** of OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of the Food and Drugs, 21 CFR part 814 is amended as follows:

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

1. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

2. Section 814.39 is amended by revising paragraph (a) introductory text, by removing paragraph (a)(4) and redesignating paragraphs (a)(5) through (a)(8) as paragraphs (a)(4) through (a)(7), respectively, and by adding paragraph (f) ^{before the concluding text} to read as follows: ^{of 3 per C.A.N. miss}

§ 814.39 PMA supplements.

(a) After FDA's approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA, unless the change is of a type for which FDA, under paragraph (e) of this section, has advised that an alternate submission is permitted or is of a type which, under section 515(d)(6)(A) of the act and paragraph (f) of this section, does not require a PMA supplement under this paragraph. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device:

* * * * *

(f) Under section 515(d) of the act, modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA do not require submission of a PMA supplement under paragraph (a) of this section and are eligible to be the subject of a 30-day notice. A 30-day notice shall describe in detail the change, summarize the data or information supporting the change, and state that the change has been made in accordance with the requirements of part 820 of this chapter. The manufacturer may distribute the device 30 days after the date on which FDA receives the 30-day notice, unless FDA notifies the applicant within 30 days from receipt of the notice that the notice is not adequate. If the notice is not adequate, FDA shall inform the applicant in writing that a 135-day PMA supplement is needed and shall describe what further information or action is required for acceptance of such change. The number of days under review as a 30-day notice shall be deducted from the 135-

supplement review period if the notice meets appropriate content requirements for a PMA supplement.

* * * * *

Dated: 10/1/98

October 1, 1998

78
per
Ann
made

William B. Schultz

William B. Schultz
Deputy Commissioner for Policy

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Lisa Borders